PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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Termijn: 04.01.05
Rec.: - 2 NOV. 2004
Opbergen:

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PCT

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	04.11.2004
Applicant's or agent's file reference P26395PC00/JPO	**REPLY DUE** **within 2 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/NL 03/00699	16.10.2003	18.10.2002

International Patent Classification (IPC) or both national classification and IPC
A61M5/32

Applicant
ADVANCED PROTECTIVE INJECTION SYSTEMS B.V. et Al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis. For an informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 18.02.2005

Name and mailing address of the international preliminary examining authority:

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I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-18 as originally filed

Claims, Numbers

1-19 as amended (together with any statement) under Art. 19 PCT

Drawings, Sheets

1/11-11/11 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: English , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☒ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.
   ☐ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 17-19

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 17-19

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	16
Inventive step (IS)	Claims	1-15,16
Industrial applicability (IA)	Claims	

2. Citations and explanations

   see separate sheet

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: US-A-5 221 262 (KITE JOHN P) 22 June 1993 (1993-06-22)

D2: WO 00/27450 A (MDC INVEST HOLDINGS INC ;BOTICH MICHAEL (US); HALSETH THOR (US)) 18 May 2000 (2000-05-18)

1. First subject-matter, **claims 1-15**

1.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-15 does not involve an inventive step in the sense of Article 33(3) PCT.

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (see column 3, line 62 - column 4, line 43, Figures 1,2 and 4)(the references in parenthesis applying to this document):

an injection syringe (10) with retractable needle (18) having

- a liquid container (11) with an outlet opening,
- a needle (18) with needle mount (22) which is or can be secured in or on the outlet opening of the liquid container (11);
- a piston (32) which can move inside the liquid container (11) and has a piston head (39), to which a piston rod (34) is or can be secured, wherein the needle mount (22) of the needle (18) and the piston head (39) comprise coupling means which are designed so that they can be unmistakably coupled to one another;

a blocking means (31) which is designed to block the needle mount (22) in the outlet opening, which blocking means (31) can only be unblocked by the needle mount (22) with needle (18) being retracted into the liquid container (11) by the piston (32) being moved away from the outlet opening after the needle mount (22) has been coupled to the piston head (39);

- a blocking means which is designed to block the needle mount (22) in the outlet opening, the blocking means being designed in the form of one or more resilient lugs (31) on the needle mount (13) which can be received in corresponding recesses in the liquid container (11) (needle support (17) is fixed to needle mounting (13) of container (11) - see column 4, lines 2-4).

1.2 The subject-matter of claim 1 therefore differs from this known injection syringe

only in that:
the coupling means of the needle mount of the needle comprise at least two ribs which are connected to one another at a connection point on the side which faces the piston head.

Consequently, the subject-matter of claim 1 is new with respect to Article 33(2) PCT.

1.3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 does not involve an inventive step in the sense of Article 33(3) PCT.

In particular it can be deduced from D1 that referring to:
the part of needle housing (22) which extends on the side which faces the piston head can be regarded as a rib in the same sense as defined in claim 1 at line 15 of the present application. The fact that D1 discloses only one rib against "at least two ribs" present merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to save the problem posed, namely providing means to prevent the risk of injury on the needle.

Therefore, the subject-matter of claim 1 does not involve an inventive step with respect to Article 33(3) PCT.

1.4 Dependent **claims 2-15** do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see for instance:

D1, column 4, lines 28-32, Figure 4 for **claim 2,3,6**;
D2, page 4, lines 1-4, Figures 1B, 1C for **claims 10,11 and 15**;

The remaining dependent claims just refer to obvious matter.

2. Second subject-matter, **claim 16**

The subject-matter of claim 16 is not new in view of D1, compare paragraph 1.1 above. The requirements of Article 33(2) PCT are thus not met. Moreover, claim 16 is formulated such that the needle mount is intended to be *suitable for* an injection syringe according to any preceding claim without indicating any specific features which would

make the needle mount suitable for such a purpose. Additionally, the syringe of claim 1 already comprises a needle mount. As such, claim 16 does not meet the requirements of Article 6 PCT.

3. Remarks

3.1 As explained below, some of the features in the apparatus claims 1 and 16 relate to a method of using the apparatus rather than clearly defining the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claims, contrary to the requirements of Article 6 PCT.

3.1.1 In particular, in the present definition of claim 1 it is attempted (see e.g. lines 4,7,9,11,20) to define the parts of an injection syringe, namely needle (2), piston (5), rod (7) or coupling means, by using functional terms such as "can be secured in or on" (line 5), "can move" (line 7), can be secured" (line 9), "can be unmistakably coupled" (lines 11,12) or "can be received in corresponding recesses" (lines 20,21), "can only be unblocked" (line 22), respectively, in place of technical details by reference to which it may be clearly explained how the injection syringe is constructed.

3.1.2 Also the features of the injection syringe as claimed in claim 4 relate to a method of using the syringe thus rendering unclear the intended limitations.

3.2 Moreover, claim 1 does not meet the requirements of Article 6 PCT, insofar as the definition of "unblocking the blocking means (14)" (see lines 22-25) is not clear. This could be overcome by the following amendment: "..., which blocking means (14) can only be unblocked by retraction of the needle mount (8) and needle (2) into the liquid container (3) by moving the piston (5) away from the outlet opening (4) after ...".

3.3 Claim 16 defines a needle mount intended to be *suitable for* an injection syringe (see point 2 above). As such, there are no technical features which would clearly define the scope of this claim.